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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,700	10/18/2001	Roger Samzelius	P01,0353	8626

26574 7590 07/22/2003

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EXAMINER

WEISS JR, JOSEPH FRANCIS

ART UNIT	PAPER NUMBER
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3761

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DATE MAILED: 07/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/982,700

Applicant(s)  
Samzelius

Examiner  
Joseph Weiss

Art Unit  
3761



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Oct 18, 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some\* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 6) ☐ Other:

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## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 8-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 8 recites the limitation "said measurement system" in lines 11-12. There is insufficient antecedent basis for this limitation in the claim.

4. Claim 8 recites the limitation "said at least one parameter" in line 12. There is insufficient antecedent basis for this limitation in the claim.

In regards to claims 9 & 10, the redundancy of the trigger requirement being trigger sensitive/enabled renders the claim indefinite, the concept of a value being designated as a trigger is just that, its sensitive at the trigger point, please clarify and rephrase to set forth what applicant is attempting to claim and define by use of this language and/or point to that portion of the written description that can justify use of this language as it currently stands, if possible.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-4, 7-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ward et al (US 6360740) .

Ward substantially discloses the instant application's claimed invention to include a tubing system (8), a pneumatic unit (6), a sensor system (22/24) consisting of at least one flow meter and a pressure meter (see col. 5 lines 36-38), a control unit (30) having a first determination unit connected to said sensor system that is fully capable of receiving a measurement signal representing at least one parameter (30, note col. 5 lines 49-54), and fully capable of determining a first respiration indication signal based upon the parameter, a comparator (30, note col. 5 lines 55-57, optimization) connected to the first determination unit that is fully capable of receiving said first respiration indicting signal with a trigger requirement (the programmed data input by the physician), and generating a comparator output (the results of the comparison of physician input data to the measures data that results in optimization of operation of the device) indicative of whether or not the trigger requirement has been meet and a signal generator (30, note its in two way electronic communication within itself and the various components of the system) supplied with the comparator which is fully capable of generating a trigger signal for controlling triggering respiratory phases dependent on comparator output, but does not explicitly disclose an excitable cell detector (18) adapted to detect excitable cell signals related to the respiration of the user, a

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second determination unit (26) supplied with said excitable cell signals which determines a second respiration indicator signal based upon excitable cell signals and an adapter unit (30) supplied with said second respiration indicator and connected to said comparator, said adaptation unit adapting said trigger requirement dependent on said second respiration indicator signal and supplying said trigger requirement to said comparator (note col. 5 lines 55-57), one or ordinary skill appreciating that the control unit being a programmable based system all of the functions disclosed are indicative of various aspects of its program, i.e. algorithms and thus serving as the basis of obvious equivalency of structure since they are same functions and capabilities as set forth by applicant

In regards to claim 9, the pre-programmed values of the ventilator serve as a trigger for operation of the device & as such are "trigger sensitive and/or enabled" and the process of optimization of the device's operation relative to the feedback obtained from a user via the first and second respiration signals & adaption unit allows for any change of any values that serve as a trigger.

In regards to claim 11, the excitable cell signal detector (18) is disclosed as a nerve signal sensor (See col. 4 line 66-col. 5 line 3).

In regards to claim 12, the excitable cell signal detector (18) is disclosed as a phrenic efferent signal sensor (See col. 4 line 66-col. 5 line 5).

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In regards to method claims 1-4 & 7, one of ordinary skill in the art would appreciate that the method steps claimed in the instant application would naturally flow from the device disclosed in the prior art as noted above and therefore are rejected herein above with respect to claims 8-15.

7. Claims 5-6 & 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sinderby (US .

In regards to claim 13, Ward substantially discloses the instant application's claimed invention, but does not explicitly disclose a muscle signal sensor. However, Sinderby disclose such (See Fig 8). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Sinderby and used them with the device of Ward. The suggestion/motivation for doing so would have been to optimize sensitivity and accuracy of ventilation support by direct diaphragm monitoring. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

In regards to claim 14, the suggested device discloses the muscle signal sensor as being a diaphragm electromyography sensor

In regards to claim 15, the suggested device discloses the sensor as comprising a esophageal catheter having an array of sensing electrode.

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In regards to method claims 5-6, one of ordinary skill in the art would appreciate that the method steps claimed in the instant application would naturally flow from the device disclosed in the prior art as noted above and therefore are rejected herein above with respect to claims 8-15.

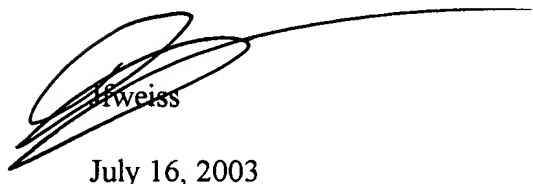
*Conclusion*

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6588423, 6584347, 6357438, 6224562, 5820560, 5785051, 5660171, 5584290, 5390666, 5161525, 4960133, 4827935

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Joseph F. Weiss, Jr., whose telephone number is (703) 305-0323. The Examiner can normally be reached from Monday-Friday from 8:30 AM to 4:30 PM.

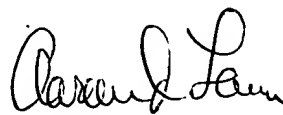
If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Weilun Lo, can be reached at telephone number (703) 308-1957. The official fax number for this group is (703) 305-3590 or x3591.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0858.



J. F. Weiss

July 16, 2003



Aaron J. Lewis  
Primary Examiner